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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,955	10/28/2003	Robert Naylor Laurie	P07351US01/SJW	3799

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STITES & HARBISON PLLC  
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ALEXANDRIA, VA 22314

EXAMINER
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TCHERKASSKAYA, OLGA V

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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08/18/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

iplaw@stites.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/693,955	<b>Applicant(s)</b> LAURIE ET AL.
	<b>Examiner</b> OLGA V. TCHERKASSKAYA	<b>Art Unit</b> 1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04/08/2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 8, 10-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,8,10,13 and 15 is/are allowed.
- 6) ☒ Claim(s) 11,12,14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
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## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment to Claims and Applicant's Arguments/Remarks, all filed on April 8, 2011 is acknowledged.

Claims 1, 3, 4, 8, 10-15 and 17-20 are pending in this action. Claims 11, 12 and 14 have been amended. New claims 17-20 were added. Claims 1, 3, 4, 8, 10, 13 and 15, were previously allowed. Claims 11, 12, 14, 17-20 are currently under consideration. Claims 11, 12, 14, 17-20 are rejected.

The description of "continuous process" provided in Declaration under 37 C.F.R. §1.132 filed on April 8, 2009 is acknowledged.

### **Continued Examination Under 37 CFR 1.114**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 8, 2011 has been entered.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 11, 12, 14, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard U.S. 4,335,116 (hereafter referred to as Howard) and Baran et al. J. Braz. Chem. Soc. (2002) 13(5):576-582.**

Howard teaches the method for preparing stable mineral-containing therapeutic compositions in the form of aqueous solutions for administration to domesticated animals, such as livestock (Abstract). The compositions comprise water-soluble organometallic complexes of ions of zinc, copper, manganese, chromium and selenium (Col. 4, Ln. 51 - Col. 5, Ln. 5). Solutions may be prepared to allow each milliliter thereof to contain: from about 0.1 to about 25 mg of zinc; from about 0.1 to about 10 mg of copper; from about 0.1 to about 20 mg of manganese; from about 0.01 to about 5.0 mg of chromium; and from about 0.1 to about 12.0 mg of selenium (Col. 5, Lns. 26-35; Col. 9, Lns. 23-30). These amounts are equivalent to 72 mg/ml of the combined zinc, copper, manganese, chromium and selenium components, and the "72 mg/ml" metal concentration of Howard reads on Applicant's metal concentration of "60 mg/ml" recited in instant claims 11, 12 and 14. Furthermore, Howard provides a detailed description of preparing said trace element stock solutions with maximum concentration of 74 mg/ml, Me/EDTA stock complexes with maximum concentration of 45 mg/ml, and selenium stock solutions with maximum concentration of 155 mg/ml (Example 1; Col. 7. Ln. 25 - Col. 8, Ln. 16 as applied to Claims 17 and 18). Mixing said solutions provides injectable solutions with desired concentration and composition of

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minerals (Col. 8, Lns. 5-15, Col. 9, Lns. 23-30 as applied to Claims 17-20). Howard does not disclose wherein the method comprising preparing a single injectable solution in a continuous process.

Baram discloses the method for preparing a single solution comprising multiple trace elements in a continuous process (Page 577, right Lns. 45-51; Page 578, left Lns. 1-10) that can be concentrated up to the crystallization of the product (Page 578, left Lns. 1-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize method for preparing trace elements solution as taught by Baran employing trace elements taught by Howard, because Baran teaches that such method provides mixed-metal complexes with high yields and in a very pure form as confirmed by chemical and spectroscopic analysis.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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**Claims 11, 12, 14, 17-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,638,539.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a method of preparing solutions comprising multiple metal elements. The solutions are prepared by dissolving metal compounds directly in a solvent comprising disodium EDTA. The main difference between the instant application and the prior patent is that the instant application also claims the solutions being injectable.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to administrate mixed-metal solution as injections. One would have been motivated to do so for improving effectiveness of chelation therapy and improve delivery of trace elements to the patient.

**Claims 11, 12, 14, 17-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-23 of U.S. Patent No. 7,285,292.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a method of preparing solutions comprising multiple metal elements at about 60 mg/ml. The solutions are prepared by dissolving metal compounds directly in the aqua solvent in the presence of EDTA. The main difference between the instant application and the prior patent is that the prior patent

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claims use of sodium EDTA, potassium EDTA and/or EDTA acid, while the instant application claims disodium EDTA and/or EDTA acid.

It is a position of the Examiner that said variation of ionic strength of the solution (e.g., by varying EDTA salts) is not so distant so as to impart a patentable distinction over the prior art. Further, complexometric titration of metal solutions with disodium EDTA is well within the level of the skilled artisan (e.g., Zaitoun et al., J. Phys. Chem B 1997, 101:1857; Yu et al., Water, Air and Soil Pollutions 1994, 75:205), and experimental parameters required for avoiding cationic precipitation and/or ensuring solution stability (e.g., pH, ionic strength, EDTA salt/acid, concentrations/compositions, etc) may be elucidated via routine experimentation to achieve an optimal outcome.

### **Response to Arguments**

Applicant's arguments filed April 8, 2011 have been fully considered but they are not persuasive.

#### **Claim Rejections - 35 U.S.C. 103(a) over Howard, U.S. 4,335,115:**

Applicant argued, "...Howard fails to provide an enabling disclosure for one of ordinary skill in the art to produce a trace element solution having a concentration of 60 mg/ml or greater."..." Howard is completely silent with regard to providing any direction on how to produce a trace metal solution having the claimed concentrations."

This argument has been considered but was not deemed persuasive. Howard provides a detailed description of preparing said trace element stock solutions with maximum concentration of 74 mg/ml, Me/EDTA stock complexes with maximum concentration of 45 mg/ml, and selenium stock solutions with maximum concentration

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of 155 mg/ml (Example 1; Col. 7. Ln. 25 - Col. 8, Ln. 16 as applied to Claims 17 and 18). Combination of above solutions is used to provide injectable solutions comprising multiple trace elements stabilized by complexes with EDTA with desired concentration of minerals (Col. 8, Lns. 5-15, Col. 9, Lns. 23-30 as applied to Claims 17-20). Howard also teaches that pH adjustment by adding HCl/NaOH might be required to avoid precipitation (Col. 7, Lns. 35-65).

Taking this into consideration it is a position of the Examiner that the determination/modification of experimental conditions for avoiding the metal precipitation (e.g., pH, ionic strength, HCl/NaOH, etc) is well within the level of the skilled artisan, and may be obtained via routine experimentation to achieve an optimal outcome.

### ***Conclusion***

Claims 11, 12, 14, 17-20 are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga V. Tcherkasskaya, Ph.D. whose telephone number is (571)270-3672. The examiner can normally be reached on 8am - 5 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for



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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/OLGA V. TCHERKASSKAYA/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner  
Art Unit 1615